MAY 11 2000

K 000965

510(k) - Premarket Notification

Multi-Axial Cross (MAC) Connectors - Additional Sizes

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Terry Sheridan Powell
Date of Summary Preparation:	March 16, 2000

Device Identification

Proprietary Name:	Multi-Axial Cross (MAC) Connector
Common Name:	Spinal Fixation Appliance
Classification Name and Reference:	§888.3050 Spinal Interlaminal Fixation Orthosis §888.3050 Pedicle Screw System

Predicate Device Identification

Howmedica Osteonics Corp.'s own, commercially-available Multi-Axial Cross (MAC) Connectors.

Device Description

This submission addresses a line extension for smaller sizes of the MAC Connector. These smaller sizes include three new multi-axial sizes, and four new monoblock (i.e., one-piece) sizes. In addition to sizing, the new sizes differ from the predicate MAC Connectors as follows:

- The J-hooks face the same direction, rather than facing each other,
- The J-hook opening is slightly larger,

- The Monoblock sizes (17, 20, 23, 26mm) feature a one-piece design, rather than the multi-axial joint.

Intended Use

The intended uses for the subject MAC Connectors remain unchanged from those of the predicate MAC Connectors. The subject devices continue to be single-use devices which are sold non-sterile, and are intended for use with other components of the commercially-available Osteonics® Spinal System. The MAC Connectors are available in ASTM F-136 Ti-6Al-4V ELI Alloy only which is the same alloy as that of the Osteonics® Spinal System. The Osteonics® Spinal System is intended for fixation of the T4-S2 spine. All bone screws are indicated for sacral fixation, or for limited pedicular fixation.

The subject MAC Connectors may be used in spinal applications where additional stability for the device construct is desired by the surgeon. The MAC Connectors allow a spinal construct on one side of the spine to be joined to another construct on the other side of the spine. The joining is intended to provide additional resistance to physiological forces such as unequal lateral loads, rotation, and isolated torsional movements.

The specific indications and contraindications of the Osteonics® Spinal System, including the subject additional components, are stated in the following subsections.

Indications

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System is indicated for:

- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Previously failed fusion
- Spinal tumor

Pedicular Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics® Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
- In addition, the Osteonics® Spinal System is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below)with removal of the implants after the development of a solid fusion mass.

Statement of Technological Comparison

The subject and predicate MAC Connectors are manufactured from the same material. The indications for use of the subject and predicate MAC Connectors are identical. The subject and predicate MAC Connectors vary slightly with regard to overall size, hook-opening size, hook direction and---in the case of the monoblock component—one-piece versus multi-piece style. These design differences, however, have been adequately justified via mechanical testing, FEA, and dimensional analyses, and have been shown to have no significant effect on safety or effectiveness as compared with the predicate MAC Connectors.

Performance Data

A risk analysis was performed to evaluate the potential risks associated with these modified and smaller MAC Connectors. The strength of the subject connectors themselves, the continued strength of the rod-to-connector interface (axial resistance, center bolt pull-apart/torque/strength), and the possible effect of the new components on the stress distribution in the Osteonics® Spinal System (screws/rods/connector) construct were considered. The Engineering Analysis employed dimensional analyses, FEA, and mechanical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Ms. Terry Sheridan Powell
Regulatory Affairs Team
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K000965
Trade Name: Multi-Axial Cross (MAC) Connector
Regulatory Class: II
Product Code: MNI, MNH and KWP
Dated: April 24, 2000
Received: April 25, 2000

Dear Ms. Powell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000965

Device Name: Multi-Axial Cross (MAC) Connector®

Indications For Use:

The subject components are single-use devices which are sold non-sterile and are intended for use only with the other titanium alloy components of the commercially-available Osteonics® Spinal System.

The uses for the commercially-available Osteonics® Spinal System are as follows:

As a posterior, non-pedicle screw system of the T4-S2 spine, the Osteonics® Spinal System is indicated for:

- Long and short curve scoliosis
- Vertebral fracture or dislocation
- Spondylolisthesis
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Previously failed fusion
- Spinal tumor

Pedicular Use:

- When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Osteonics Spinal System is indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

- In addition, the Osteonics Spinal system is indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, having fusions with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below)with removal of the implants after the development of a solid fusion mass.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Lockwood

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000965

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)